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Post-Concussion Tools to Assist with Assessment, Treatment, and Return to Duty

PRINCIPAL INVESTIGATOR:
Dr. Angus Rupert

CONTRACTING ORGANIZATION:
Henry M. Jackson Foundation for the Advancement of Military Medicine
Bethesda, MD 20817

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6. AUTHOR(S)
Dr. Angus Rupert

E-Mail: angus.h.rupert.civ@mail.mil

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Henry M. Jackson Foundation for the Advancement of Military Medicine

6720A Rockledge Dr.
Suite 100
Bethesda, MD 20817

8. PERFORMING ORGANIZATION REPORT NUMBER

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14. ABSTRACT
Dizziness and instability are common outcomes of concussion and mild Traumatic Brain Injury (mTBI). Such problems decrease functional ability and patient safety, while adversely affecting cognition and affect. The latest objective tests of balance/dizziness are not routinely used to aid assessment and diagnosis, nor to monitor recovery. This project intends to fill these gaps. We will develop an enhanced quantitative test battery for evaluating neurophysiological balance dysfunction associated with concussive events or mTBI. This project will deliver a portable initial screening instrument for immediate field assessment after injury, and a battery of sensitive clinic-based tests for monitoring results of therapy during the recovery period. Test sensitivity will be established on groups of military personnel who have or have not been exposed to blast (without concussion) or concussion (without blast). Specificity for differential diagnosis will be established by comparing to individuals diagnosed with PTSD and normal subjects attempting to malinger. This project will be coordinated with another funded effort to assist patients through the entire period of injury and recovery, allowing for initial assessment to aid diagnosis, objective monitoring of recovery, the establishment of criteria for deciding about fitness for returning to duty, and the development of an enhanced program of rehabilitation. A treatment program will be developed in coordination with our other funded effort, which emphasize individualized, automated training to decrease sway under conditions of enhanced balance feedback, to coordinate head-eye movement reflexes normally again, and to balance normally while cognitively engaged in a challenging mental task.

15. SUBJECT TERMS Dizziness, balance dysfunction, vestibular, sway, instability, falls, physiotherapy, tactile cueing, vibrotactile, tactors, mild traumatic brain injury, mTBI, concussion, rehabilitation, screening, vestibular assessment.

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1. **INTRODUCTION:** Mild TBI is closely associated with balance dysfunction. The tests and devices used to assess and treat patients exposed to concussive events are not available in-theater. The stated goals of the project are; 1) the delivery of a portable initial screening device for immediate field assessment after injury, 2) improved test battery for monitoring treatment during the physiotherapy and 3) development of an enhanced program of rehabilitation.

2. **KEYWORDS:** Dizziness, balance dysfunction, vestibular, sway, instability, falls, physiotherapy, tactile cueing, vibrotactile, tactors, mild traumatic brain injury, mTBI, concussion, rehabilitation, screening, vestibular assessment.

3. **ACCOMPLISHMENTS:**

- **What were the major goals of the project?**

The stated overarching goals of the project are; 1) the delivery of a portable initial screening device for immediate field assessment after injury, 2) improved test battery for monitoring treatment during the therapy and 3) development of an enhanced program of rehabilitation.

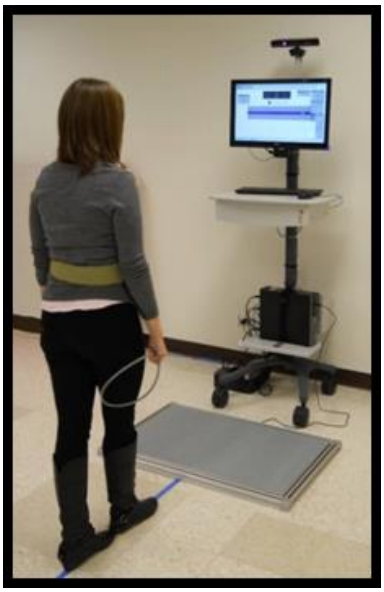
- **What was accomplished under these goals?**

This project developed the technology of an enhanced balance platform for both assessing and treating patients with balance dysfunction. The platform device incorporated novel tactile cueing, which was adopted from an aviation application, and improved to provide balance therapy treatment for a variety of balance compromised patients. Furthermore the device is portable meeting the primary goal of the project. The novel tactile cueing provided patients a more rapid rehabilitation to baseline function as described below.

- **Major Goals:**

1) Delivery of Portable Screening Test: Working in conjunction with the SBIR process this project developed, and continuously improved during the period of performance, a balance rehabilitation platform that can also assess initial balance performance. There were two companies involved – Engineering Acoustics Inc. (EAI) which produced the Sensory Kinetics (SK) platform and Balance Sense Inc produced a platform named Balance Sense (BS). Both companies delivered a device consisting of the following components: a) a force plate to measure center-of-pressure (COP); b) visual screen to provide GUI (Graphical User Interface) displaying COP and test information and c) tactile cueing belt. These devices were developed

during the first two years of the project while the IRB was undergoing joint approval by Army and Navy IRBs.



Prototype SK Balance System (left) comprising of a visual display, force plate, inertial and camera sensors and a torso worn tactile belt. Heel to toe functional task using tactile, audio and visual feedback (right).

These devices were assessed for efficacy as a tool to provide rehabilitation of patients and continued assessment of performance during the rehabilitation process. Based on the performance as a rehabilitation tool, a commercial company Biodex has purchased BS and the tactile cueing technology to commercialize and deliver to the physiotherapy community a product for assessment and treatment of patients with balance dysfunction.

The two devices were delivered to clinical rehabilitation centers for evaluation as a rehabilitation tool and to obtain feedback from the physiotherapy community to refine the product for commercial development.

2) A stated sub-goal/specific objective was to “distinguish different types of head trauma”. That is, could the device(s) and associated tests determine whether injury was due to blast concussion vice direct blow to the head. The research carried out under this project did not

succeed in distinguishing between these types of head injury. The testing is described in more detail in following section.

3) Development of an enhanced program of rehabilitation. Data from two test sites was analyzed by Dr. Heather McGee (Henry Jackson Foundation statistician). The Navy Medical Center San Diego (NMCSD) physiotherapy department evaluated both SK and BS platforms whereas the Florida Ear and Balance Center evaluated only the BS platform. Although the two centers used many of the same tests for evaluation it was not possible to pool the data from both centers since the protocols differed slightly and the patient populations differed.

Both centers used the Neurocom Equitest balance platform as the gold standard, against which the SK and BS force plate platforms were compared, to evaluate dynamic postural equilibrium. An evaluation test common to both centers included the Berg Balance Scale which is a measure of falling. The Sensory Organization Test (SOT) and the Berg Balance Test are described in appendix A. The final report statistics and summaries prepared by Dr McGee for NMCSD and Balance Sense are as follows:

A. **Summary of Balance Sense Findings**

The total participant sample consisted of 25 civilian subjects (8 males, 17 females). Subjects ranged in age from 51 to 84 years with a mean age of 71.64 (SD = 8.70).

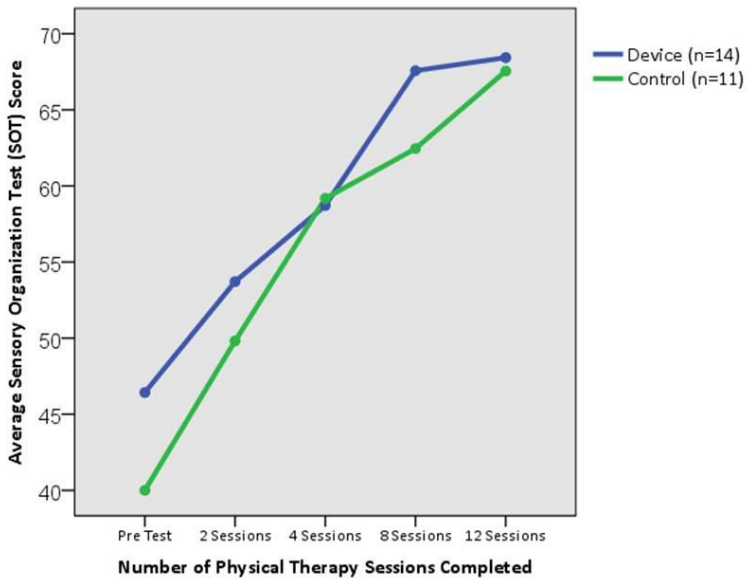
Sensory Organization Test (SOT)

Mean Raw SOT scores at each testing occasion are reported by group (Device, Control) below. A 2-way ANOVA (2X5) was conducted to examine the effects of group and number of physical therapy session completed on Sensory Organization Test (SOT) Composite scores. No significant effect was found for the main effect of Group, $F(1, 23) = .68$, $p = .42$ or the interaction between group and number of physical therapy sessions completed, $F(2.58, 59.27) = .90$, $p = .43$. A significant main effect was found for number of sessions completed, $F(2.58, 59.27) = 43.81$, $p < .001$, *partial* $\eta^2 = .66$. The results suggest that participants showed improvement in SOT Composite scores as the number of physical therapy sessions completed increased, regardless of whether they were in the Device or Control group. Average SOT Composite scores for Group by Number of PT Sessions Completed are displayed in the figure below. Percent of change found device group realizing improvement within the first 2 physical therapy sessions over 7 days with max improvement after 8 sessions over 4 weeks. Controls reached max improvement after 12 sessions over 6 weeks.

Mean Raw SOT Scores by Group

	Group	*Mean*	*SD*	*95% CI*		*N*
				Lower	*Upper*	
Pre Test	**Device**	46.43	10.31	40.51	52.34	14
	Control	40.00	11.19	33.33	46.67	11
2 Sessions	**Device**	53.71	12.87	45.81	61.63	14
	Control	49.82	15.96	40.90	58.73	11
4 Sessions	**Device**	58.71	9.60	52.89	64.54	14
	Control	59.18	11.66	42.61	65.76	11
8 Sessions	**Device**	67.57	10.39	61.35	73.79	14
	Control	62.45	12.28	55.44	69.47	11
12 Sessions	**Device**	68.43	11.48	62.14	74.72	14
	Control	67.55	11.25	60.45	74.64	11

Raw Average SOT Composite Scores



SOT Condition 5 Fall/No fall

A variable was created that dichotomized participants' SOT Condition 5 performances based on whether or not the participant fell during the trial (Fall or No Fall).The table below shows SOT Condition 5 Fall and No Fall data by Group (Device vs. Control) for Pre Test, 2 Sessions, 4 Sessions, 8 Sessions, and 12 Sessions. The table also shows the change in number of No Falls from Pre Test to each subsequent testing session for the Device and Control groups. In the Device group the number of 'No Fall' participants increased by 5 from Pre Test (1 No Fall) to 2 Sessions (6 No Fall), whereas the number of 'No Fall' participants in the Control group did not change from Pre Test (3 No Fall) to 2 Sessions (3 No Fall). As can be seen in the table, the Device group displays more early movement from 'Fall' to 'No Fall' than the Control group.

Condition 5 SOT Fall and No Fall by Group Physical Therapy Sessions

	Group	***N***	***Fall***		***No Fall***		***Change in # No Falls from Pre Test***
			n	***%***	***n***	***%***	
Pre Test	**Device**	14	13	93%	1	7%	
	Control	11	8	73%	3	27%	
2 Sessions	**Device**	14	8	57%	6	43%	+5
	Control	11	8	73%	3	27%	+0
4 Sessions	**Device**	14	6	43%	8	57%	+7
	Control	11	7	64%	4	36%	+1
8 Sessions	**Device**	14	4	29%	10	71%	+9
	Control	11	7	64%	4	36%	+1
12 Sessions	**Device**	13	4	31%	9	69%	+8
	Control	11	2	18%	9	82%	+6

Berg Balance Scale

Berg Balance Scale Risk Categories (Low Fall Risk, Medium Fall Risk, High Fall Risk) were computed for each participant. The Berg Balance Scale Risk Category by Group at Pre Test table below shows the Berg Balance Scale Risk Category data by Group (Device vs.

Control) at Pre Test. As can be seen in the table, 13 participants started (at Pre Test) in the Low Fall Risk Category (9 from the Device group, 4 from the Control Group). Since these Low Risk participants could not reduce their Risk Category in subsequent trials (i.e., they were already in the lowest risk category at Pre Test), they were excluded from further analyses that examined whether or not participants moved into a lower risk category (i.e., reduced their Fall Risk Category) from Pre Test to after 4 PT sessions. The Berg Risk Category Movement from Pre Test to after 4 PT Sessions by Group table displays the number (and percent) of participants in each group (Device vs. Control) that reduced their Fall Risk Category after 4 PT sessions. All five subjects in the Device group that had an opportunity to move into a lower risk category after 4 PT sessions did move (i.e., 100% reduced their risk level). Alternatively, only 3 of the seven subjects in the Control group that had an opportunity to move into a lower risk category after 4 PT sessions did move (i.e., 43% reduced their risk level).

Berg Balance Scale Risk Category by Group at Pre Test.

	Fall Risk Category		
	Low	Medium	High
Group (*n*)	*n* (%)	*n* (%)	*n* (%)
Device (*14*)	9 (64%)	5 (36%)	0 (0%)
Control (*11*)	4 (36%)	6 (55%)	1 (9%)

Berg Risk Category Movement from Pre Test to after 4 PT Sessions by Group.

	Reduced Risk	Did Not Reduce Risk
Group (*n*)	*n* (%)	*n* (%)
Device (*5*)	5 (100%)	0 (0%)
Control (*7*)	3 (43%)	4 (57%)

Conclusions

Device group shows earlier improvement in Sensory Organization Test score than the control group. This indicates that vestibular input is being more efficiency utilized during compliant surface plus eyes closed conditions. Percent of change found device group realizing improvement within the first 2 physical therapy sessions over 3 days with max improvement after 8 sessions over 4 weeks. Controls reached max improvement after12 sessions over 6 weeks. An improvement in SOT scores have been linked to decrease in fall occurrence.

Device group decreased fall risk sooner than control group. Berg Balance Scale found 100% of device subjects lowered their fall risk category after 2 physical therapy sessions compared to 43% of controls who reduced fall risk category, and 57% controls who did not reduce their fall risk category during the same time frame. Likewise, Functional Gait Assessment at Pre Test found 14 subjects in the device group had the opportunity to move into a lower risk category moving from high to medium or low risk category: 10 subjects in the control group had the opportunity to move into a lower risk category. From Post Test 1 to Post Test 2, after a total of 4 physical therapy sessions within 10 days, 10 subjects or 77% of the device group had reduced fall risk compared to 2 subjects or 20% of the control group. Expanding the reporting time frame to include Pre Test through Post Test 2, finds 11/14 subjects or 79% in device group compared to control groups 1/10 or 10% improved fall risk.

SOT Condition 5 measures center-of-gravity (COG) postural sway and velocity from COG. Subject static stands shoulder width apart with eyes closed while surface sways. A new variable was created that dichotomized participants' SOT Condition 5 performances based on whether or not the participant fell during the trial (Fall or No Fall).4 At Pre Test, 18 of the 25 participants (72%) obtained a SOT Condition 5 score of zero and only four of the 25 participants (16%) were able to complete the trial without falling. All device subjects that were falling at Pre Test achieved no fall at Post Test 1: no control subjects that were falling at Pre Test achieved no fall by Post Test 1. Self Report Falls data is consistent with Condition 5 Fall/No Fall findings.

A fall is an unintentional change in position causing an individual to land at a lower level, on an object, the floor, the ground or other surface with or without injury. This includes: slips, trips, falling into other people, being lowered, loss of balance, and legs giving way. (Exclude sudden onset of paralysis, epileptic seizure, or overwhelming external force.) Self Reporting of falls found both groups reduced fall rates, but the device group reduced fall rates faster than the

control group. Eleven control and 11 device subjects had an opportunity to reduce multiple falls per day; 6 (54%) device and 1 (9%) controls reduced fall rate after 2 physical therapy sessions within 3 days; 7 (64%) device and 5 (45%) controls reduced fall rate after 4 physical therapy sessions within 14 days; 10 (91%) device and 8 (73%) controls reduced fall rate after 8 physical therapy sessions within 28 days; 11(100%) device and 10 (91%) controls reduced fall rate after 12 physical therapy sessions within 42 days. The fall rate increased post physical therapy intervention in the control group, but remained stable in the device group for 3 ½ months. At 4 ½ months physical therapy intervention 9 ((82%) and 7 (64%) retained a no fall status

Findings imply an optimal number of treatment sessions using SEMD would be 8 rather than the 12 sessions needed for the control group to achieve the same results. The device group improved SOT, reduced fall risk, and reduced fall incident at 8 interventions while the control group achieved reduction in fall incident by12 intervention physical therapy sessions.

B. **Summary of NMCSD findings**

Forty participants were recruited from the Navy Medical Research Center (NMRC) in San Diego, CA. The mean age was 28.87 (SD = 6.134) years (age was not reported for two participants). Fourteen participants were exposed to blast, 15 experienced blunt trauma, and 8 reported both trauma types (unknown for 3 participants). Seventeen participants reported a single head injury or trauma whereas 23 reported multiple injuries or exposures. Participants were assigned to three conditions: Experimental Treatment-Balance Sense (BS; N = 14), Experimental Treatment-Sensory Kinetics (SK; N = 14), or Control (N = 12). The mean number of treatments was 8.5 (SD = 2.9) for the BS group, 9.1 (SD = 3.3) for the SK group, and 8 (3.6) for the control group; 8.5 (SD = 3.2) overall.

There were a large number of missing values for all of the measures drastically reducing statistical power and may yield unreliable results for the intended mixed model analyses of variance (note that participants must have values for all design cells to be included into the analysis). Thus, the tables and graphs below present descriptive statistics so that the emerging patterns may be observed. The sensory organization test (SOT) time-to-fall (sec) measures showed a ceiling effect and thus descriptives are not presented for this measure.

<u>SOT-Condition 2 average</u>

Table 1 and Figure 1 display the descriptives by group and test point for the SOT condition 2 averages. The data show steady improvement for both the control and the sensory kinetics experimental group. Note that the groups do not appear equal at initial testing.

TABLE I. DESCRIPTIVE STATISTICS BY GROUP AND TEST-POINT FOR SENSORY ORGANIZATION TEST CONDITION 2 AVERAGE

	Test-Points; Mean (SD)		
Group	Initial	Midpoint	Final
BS	76.94 (11.98) N=12	75.81 (16.71) N=12	76.86 (16.71) N=6
C	70.43 (24.98) N=12	81.35 (19.13) N=10	92.13 (1.65) N=4
SK	77.58 (9.61) N=13	81.36 (12.50) N=12	83.48 (12.13) N=10

Note. Groups labeled BS and SK refer to experimental treatments and C is the control group.

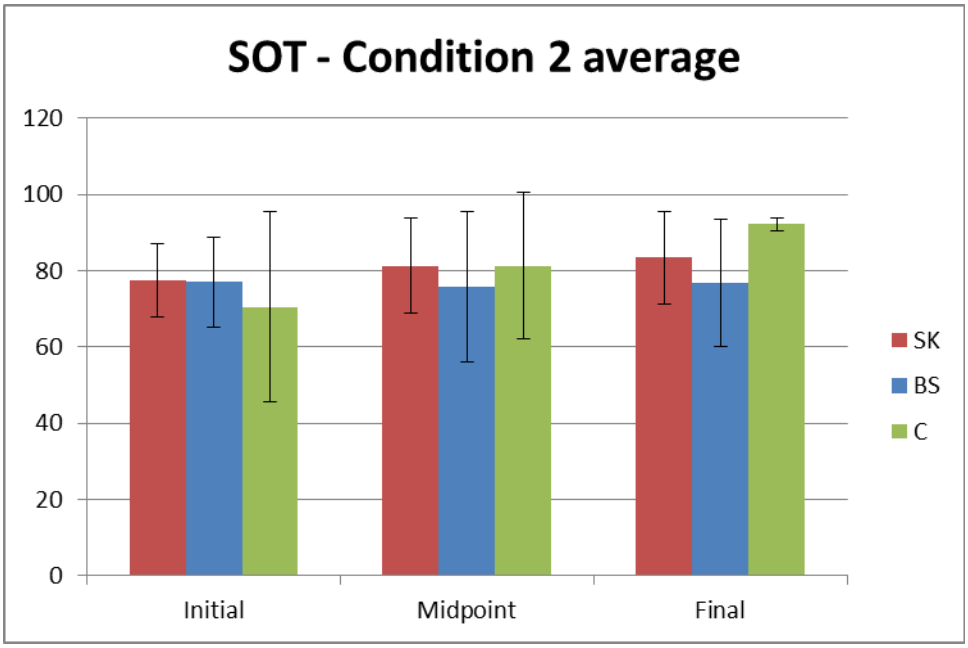


Figure 1. SOT condition 2 averages by group and test point.

SOT- Condition 5 average

Table 2 and Figure 2 display the descriptives by group and test point for the SOT condition 5 averages. The data show steady improvement for all groups. Note that the groups do not appear equal at initial testing.

TABLE II. DESCRIPTIVE STATISTICS BY GROUP AND TEST-POINT FOR SENSORY ORGANIZATION TEST CONDITION 5 AVERAGE

Group	Test-Points; Mean (SD)		
	Initial	Midpoint	Final
BS	37.04 (29.70) N=12	52.98 (28.99) N=12	58.22 (24.03) N=6
C	30.22 (26.74) N=12	54.38 (24.40) N=10	71.90 (6.26) N=5
SK	26.65 (24.94) N=13	53.78 (19.88) N=12	58.55 (23.97) N=10

Note. Groups labeled BS and SK refer to experimental treatments and C is the control group.

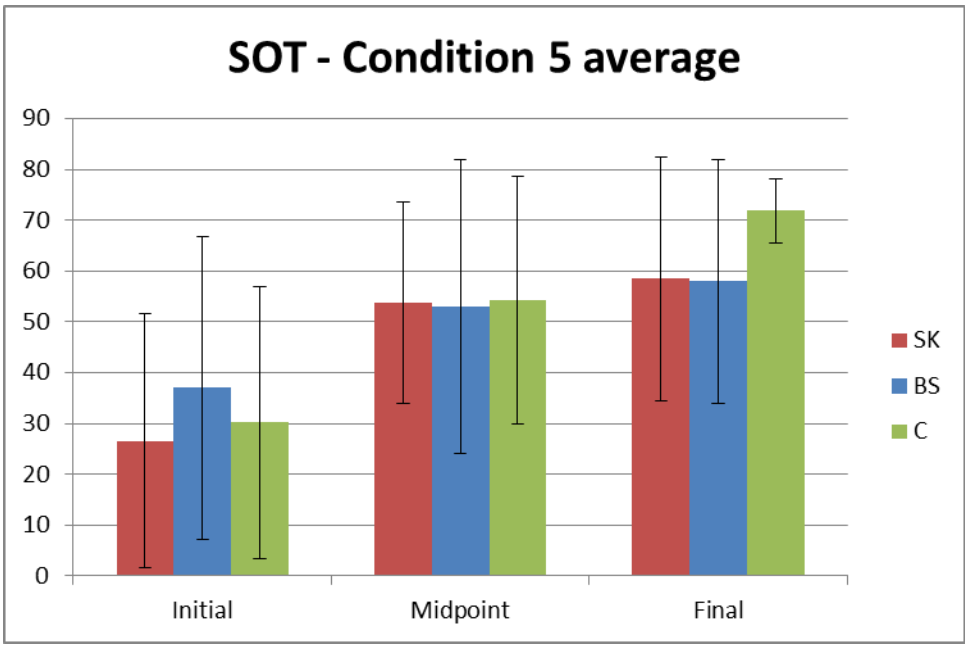


Figure 2. SOT condition 5 averages by group and test point.

Functional Gait

Table 3 and Figure 3 display the descriptives by group and test point for the functional gait scores. The data show steady improvement the control and sensory kinetics groups. Note that the groups do not appear equal at initial testing.

TABLE III. DESCRIPTIVE STATISTICS BY GROUP AND TEST-POINT FOR FUNCTIONAL GAIT

Group	Test-Points; Mean (SD)		
	Initial	Midpoint	Final
BS	25.38 (3.20) N=13	26.56 (3.43) N=9	27.20 (2.39) N=5
C	24.00 (3.84) N=9	28.33 (1.53) N=3	30.00 (0.01) N=3
SK	25.14 (3.42) N=14	27.70 (3.56) N=10	29.22 (0.83) N=9

Note. Groups labeled BS and SK refer to experimental treatments and C is the control group.

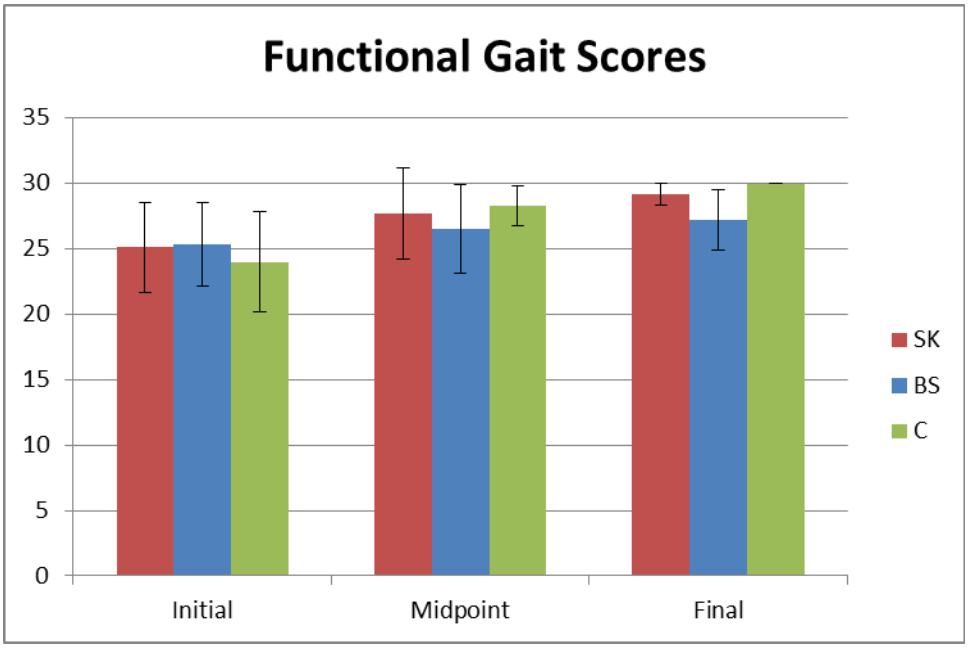


Figure 3. Function gait scores by group and test point.

Berg Balance Score

Table 4 and Figure 4 display the descriptives by group and test point for the Berg balance scores. The data show improvement for all groups however changes are minimal. Sample size is very small for control groups.

TABLE IV. DESCRIPTIVE STATISTICS BY GROUP AND TEST-POINT FOR BERG BALANCE SCORES

Group	Test-Points; Mean (SD)		
	Initial	Midpoint	Final
BS	53.22 (3.20) N=9	53.22 (3.53) N=9	55.20 (1.79) N=5
C	52.33 (4.46) N=6	55.67 (0.57) N=3	56.00 (NA) N=1
SK	52.18 (3.49) N=11	54.30 (3.09) N=10	53.88 (3.31) N=8

Note. Groups labeled BS and SK refer to experimental treatments and C is the control group.

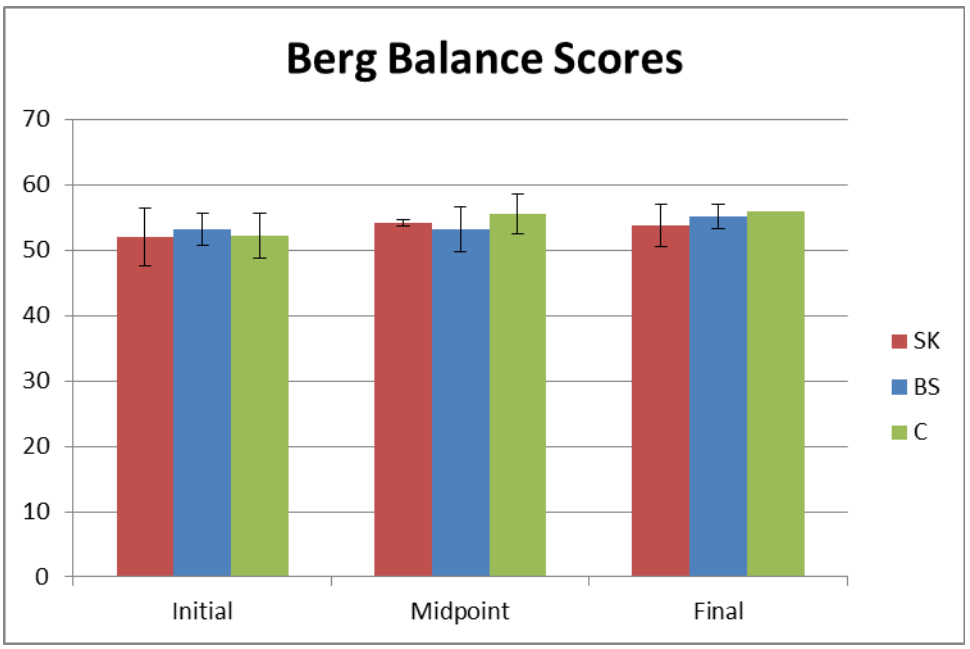


Figure 4. Berg balance scores by group and test point.

Dizziness Handicap Inventory

Table 5 and Figure 5 display the descriptives by group and test point for the Dizziness Handicap Inventory scores. The data show a dip in scores at midpoint for all groups. The

sample sizes for all groups decrease dramatically after initial testing. Note that the groups do not appear equal at initial testing.

TABLE V. DESCRIPTIVE STATISTICS BY GROUP AND TEST-POINT FOR DIZZINESS HANDICAP INVENTORY SCORES

	Test-Points; Mean (SD)		
Group	Initial	Midpoint	Final
BS	48.58 (14.27) N=12	33.00 (14.14) N=5	42.50 (19.13) N=6
C	39.86 (19.84) N=7	23.00 (12.73) N=2	39.00 (NA) N=1
SK	41.43 (13.25) N=14	27.27 (18.59) N=6	35.75 (23.46) N=8

Note. Groups labeled BS and SK refer to experimental treatments and C is the control group.

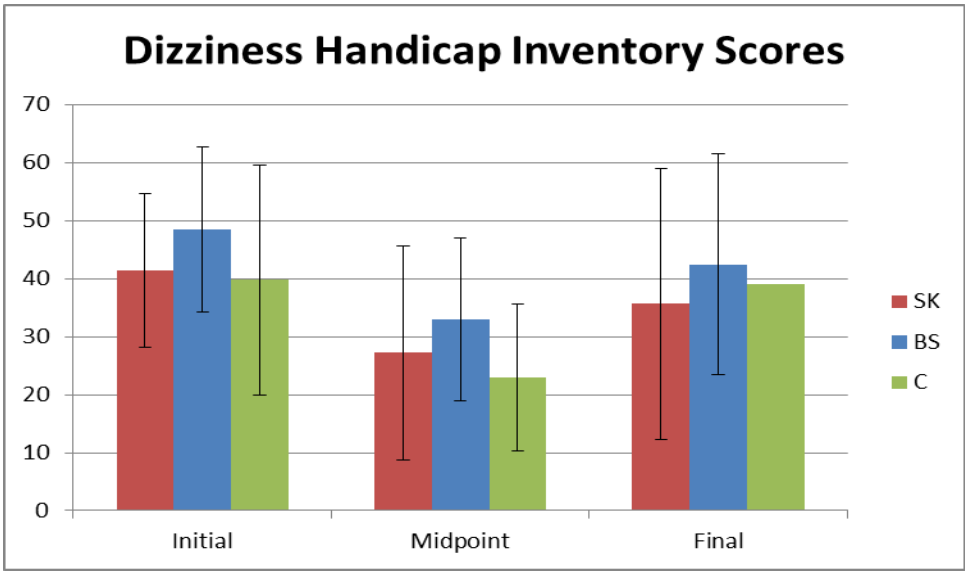


Figure 5. Dizziness Handicap Inventory scores by group and test point.

As mentioned earlier it was not possible to pool the data between centers. The Henry Jackson statistician performed the analysis on the data from both centers. The lack of statistical significance at the NMCSD site is related to the low numbers in each of the 3 groups (control, SK treatment and BS treatment). Based on data trends the statistician recommended the collection of data from additional subjects to provide the opportunity to make a definitive statement concerning the efficacy of treatment with mTBI and blast patients. The physiotherapists at NMCSD have continued to use the tactile cueing feedback device as a treatment modality following the cessation of data collection for this project. Similarly the physiotherapists at each center that has been provided with either the SK or BS platform in both the US and the United Kingdom remain enthusiastic and will continue to use the devices until commercially produced devices are available from Biodex.

This program provided a BS platform via MRMC (Medical Research and Materiel Command) to Headley Court in the United Kingdom. Headley Court is the UK equivalent of the Center for the Intrepid. The UK physiotherapists provided feedback to modify the BS device prior to the acquisition of BS by Biodex. Their letter of endorsement is included in appendix C.

- **What opportunities for training and professional development has the project provided?**

- The project supported Dr. Heather McGee to obtain her PhD in statistics from University of Rhode Island Fall 2014.
- Rockville MD meeting hosted by Henry Jackson Foundation to bring together academic physiotherapists, bioengineers in the field of balance assessment, NIH program managers for balance rehabilitation (NIDCD representatives) and Department of Defense (DoD) experts. This meeting provided a roadmap to advance the development of tactile feedback technology from the static balance platform to the ambulatory condition. This roadmap was followed via the SBIR process resulting in a phase II award December 2014. The selected company (EAI) will develop a real time, body-worn, center-of-gravity and center-of-pressure system that will provide multisensory warning of impending falls to assist in fall prevention for patients with balance dysfunction.

- **How were the results disseminated to communities of interest?**

Presentations to the scientific community were provided at the American Academy of Otolaryngolgy, Head and Neck Surgery Annual Meetings and to the neurotology and phsysiotherapy communities at the Barany Society.

▪ Demonstrations of the enhanced tactile cueing technology was provided to multiple clinics and decision-makers over the duration of the project. Presentation and demonstrations of the tactile cueing feedback balance rehabilitation were provided at the past four American Academy for Physiotherapy (AAPT) meetings. As a result of the demonstrations at the academy meetings and data collected a medical company specializing in balance rehabilitation has purchased the technology from Balance Sense and plans to market the tactile cueing balance rehabilitation in June 2015.

- **What do you plan to do during the next reporting period to accomplish the goals?**
  - Nothing to Report.

4. **IMPACT:**
   - **What was the impact on the development of the principal discipline(s) of the project?**
     ▪ The physiotherapy clinician community is the primary beneficiary of this project. Physiotherapists will benefit from the tactile cueing feedback technology developed in this research effort. The commercial company Biodex will incorporate the new technology into their product line and market tactile cueing via its worldwide medical distribution system.
     ▪ The concept of tactile cueing to provide intuitive, reflexive, automatic postural adjustments to maintain balance and prevent falls is slowly being recognized as a solution to reduce mortality and morbidity associated with falls.

   - **What was the impact on other disciplines?**
     ▪ The project provided an impetus for the companies that make tactile transducers (tactors) to improve and devise novel tactors for this biomedical application. These tactors have applications across a wide variety of military and civilian applications.

     ▪ There is an interaction between the advances made in tactile cueing to improve balance of patients and the advances made in tactile cueing for military operations to include aviation and land navigation. When demonstrations are provided to specialists in either health or military disciplines, the investigators have provided demonstrations for both applications since the universal aspect of tactile cueing as a solution to enhance situation awareness and spatial orientation is often more easily recognized when seen in disciplines outside one's own area of

expertise. Tactor technology developed for the medical applications is now used in Army aviation and ground tactile cueing systems under development.

Tactile feedback cueing is a general method that has applications beyond treating balance dysfunction. The similarities between maintaining upright stance and hovering a helicopter may not appear to be obvious but the same algorithm of tactile stimulation using a belt fitted with tactors to improve balance is the same algorithm and belt currently used by helicopter research pilots to maintain a non-visual hover in the U.S. Army.

This same tactile cueing is currently under development in a Phase II SBIR program to provide haptic information to the elderly to reduce the incidence of falls. Elderly patients who can maintain mobility without the use of canes and walkers will experience an improved social condition.

5. **CHANGES/PROBLEMS:** Nothing to report.

6. **PRODUCTS:** The project developed two competing types of balance platforms using tactile feedback cueing. In Jan 2014, one company (Balance Sense) sold their technology to Biodex which will market the technology.

- **Publications, conference papers, and presentations**

Brill, J.C., Rupert, A.H., & Lawson, B.D. (2014). Tactile situation awareness system (TSAS) as a compensatory aid for sensory loss. Proceedings of the Human Factors and Ergonomics Society 58th Annual Meeting, 1028-1032. (Paper No. 222-589.)

Grandizio, C., Lawson, B., King, M., Cruz, P., Kelley, A., Erickson, B., Livingston, L., Cho, T., Laskowski, B., & Chiaramonte, J. (2014). Development of a Fitness-for-Duty Assessment Battery for Recovering Dismounted Warriors (Report No. 2014-18).

Hastings, K. L. Vibrotactile Postural Control in Patients that have Sit-to-Stand Balance Deficit and Fall, USAARL Report No. 2010-18.

Lawson, B.D. Tactile Displays for self-motion and looming: What would Gibson think? (2014) Applied Human Factors and Ergonomics Conference, 21 July, Krakow, Poland.

Lawson, B.D. (Accepted). Unearthing Buried Mysteries in Science: Wouldn't a Steam Shovel be Better than a Spoon? Abstracted presentation, International Annual Meeting of the Human Factors and Ergonomics Society, Chicago, 27-31 October 2014.

Lawson, B.D., Kass, S.J., Dhillon, K., Milam, L., Cho, T.H., & Rupert, A.H. (2014). Identification of the military occupational specialties (MOSs) most likely to suffer mild traumatic brain injury (mTBI). 32nd Annual National Neurotrauma Symposium, 29 June to 2 July, 2014.

Lawson, B., Newman, M., Arnold, R., McGrath, B., Milam, L., & Thompson, L. (2014). Quantitative modeling and simulation of spatial disorientation events. 85th Annual Scientific Meeting of the Aerospace Medical Association, 14 May, San Diego, CA. Aviation, Space, and Environmental Medicine, 85(3), 347.

Lawson, B.D. & Rupert A.H. (2010). Vestibular Aspects of Head Injury and Recommendations for Evaluation and Rehabilitation Following Exposure to Severe Changes in Head Velocity or Ambient Pressure, Peer-Reviewed Proceedings of the International Conference on Human Performance at Sea (HPAS), Univeristy of Strathclyde, Glasgow, U.K. 16-18 June 2011; 367-380 Edited by O.Turan, J. Bos, J. Stark and J. Colwell ISBN 978-0-947649-73-9.

Lawson, B., Rupert, A., Cholewiak, R., Mortimer, B., McGee, H., Bergztrazer, D., Chiaramonte, J., Parker, J., Vasbinder, M. (2014) Conveying vehicle movement toward or away from significant objects using a simple localized touch stimulus, 85th Annual Scientific Meeting of the Aerospace Medical Association, 14 May, San Diego, CA. Aviation, Space, and Environmental Medicine, 85(3), 347.

Lawson, B.D., Rupert, A.H., & Legan, S.M. (2012-10). Vestibular and balance deficits following head injury: recommendations concerning evaluation and rehabilitation in the military setting. Fort Rucker, AL: U.S. Army Aeromedical Research Laboratory.

Lawson, B. D., Rupert, A. H., Raj, A. K., Parker, J. N., Greskovich. (2014). Invited lectures from a spatial orientation symposium in honor of Frederick Guedry, Day 1. USAARL tech report No. 2014-10.

Lawson, B. D., Rupert, A. H., Raj, A. K., Parker, J. N., Thompson, L. B., Golding, J. 2014 (In Submission). Invited Lectures from a Spatial Orientation Symposium in Honor of Frederick Guedry, Day 2. Fort Rucker, AL: U.S. Army Aeromedical Research Laboratory. USAARL Report No. 2014-

McGrath BJ, and Rupert AH. “Tactile displays: From the cockpit to the clinic” Advances in Human Factors and Ergonomics 2014. Proceedings, 5th International Conference on Applied Human Factors and Ergonomics Conference, Krakow, Poland 19-23 July 2014.

Mortimer, B., Zets, G., Mort, G., McGrath, B. Tactile Feedback for Balance Rehabilitation (accepted). International Conference on Human-Computer Interaction; 2015. Los Angeles, CA.

Rupert, A. H. & Lawson, B. D. Initial Consideration of the Feasibility and Optimal Application of Tactile Sway Cueing to Improve Balance among Persons Suffering from Disequilibrium, USAARL Report No. 2011-01.

Wetmore. S., Eibling D., Gottshall, K. Balance Problems in the Elderly. American Academy of Otolaryngolgy, Head and Neck Surgery. 11 September 2011; Washington DC.

Wetmore. S., Eibling D., Gottshall, K. Balance Problems in the Elderly. American Academy of Otolaryngolgy, Head and Neck Surgery. 13 September 2012; San Francisco, CA.

Wetmore. S., Eibling D., Gottshall, K. Balance Problems in the Elderly. American Academy of Otolaryngolgy, Head and Neck Surgery. 22 September 2014; Orlando, FL.

Wetmore. S., Eibling D., Gottshall, K., Magnusson, M., & Goebel, J. Challenges and Opportunities in Dizziness in the Older Adult. American Academy of Otolaryngolgy, Head and Neck Surgery. 28 September 2010; Boston, MA.

Wetmore. S., Eibling D., Gottshall, K. Dizziness in the Older Adult. American Academy of Otolaryngolgy, Head and Neck Surgery. 30 September 2013; Vancouver BC.

- **Journal publications**

Hancock, Lawson, Elliott, Cholewiak, van Erp, Mortimer, Rupert, Redden, & Schmeisser. (Accepted pending minor revisions). Cross-modal, multi-sensory cueing as an augmentation to human-machine interaction. Ergonomics in Design (Page numbers TBD).

Lawson, B.D., Kass, J.J., Dhillon, K.K., Milam, L.S., Cho, T.H., & Rupert, A.R. Military occupations and requisite abilities affected by mild traumatic brain injury and neurosensory injuries (Approved). Military Medicine, vol. and pages TBD.

Lawson, B.D. Rupert, A.H., & Cho, T.H. (2013). Functional Screening of Vestibular and Balance Problems Soon After Head Injury: Options in Development for the Field or Aid Station. Journal of Special Operations Medicine, 13(1), 42-48.

Lawson, B.D., Rupert, A.H., & Kelley, A.M. (In press.) Mental Disorders Comorbid with Vestibular Pathology. Psychiatry Annals, 43(7), 324-327.

Atkins, K., & Gottshall K., Treatment of Vestibular/Balance dysfunction via Multimodal Vibrotactile Visual, and Auditory Feedback, Journal of Vestibular Research, Volume 24, Numbers 2,3, 2014 p130 ISSN 0957-4271.

- **Books or other non-periodical, one-time publications**

Keshavarz, B., Hecht, H., & Lawson, B.D. (2014). Visually-induced

motion sickness: Causes, characteristics, and countermeasures. Handbook of virtual environments: Design, implementation, and applications, 2nd Edition. New York, NY: CRC Press, an imprint of Taylor & Francis Group, LLC., 647-698.

Lawson, B.D. (2014). Motion sickness symptomatology. Handbook of virtual environments: Design, implementation, and applications, 2nd Edition. New York, NY: CRC Press, an imprint of Taylor & Francis Group, LLC, 531-600.

Lawson, B.D., & Riecke, B.E. (2014). The perception of body motion. In Stanney, K.M., & Hale, K., Eds. Handbook of virtual environments: Design, implementation, and applications, 2nd Edition. New York, NY: CRC Press, an imprint of Taylor & Francis Group, LLC, 531-600.

- **<u>Other publications, conference papers, and presentations</u>**

Lawson, B.D. (2012). How I learned to stop worrying about space and start loving the vestibular organs. Invited paper following the Symposium on the Role of the Vestibular Organs in Space Exploration, Journal of Vestibular Research Online Repository, 50 pages.

Lawson, B.D. Rupert, A.H., & Cho, T.H. (2013). Functional Screening of Vestibular and Balance Problems Soon After Head Injury: Options in Development for the Field or Aid Station. Journal of Special Operations Medicine, 13(1), 42-48.

Lawson, B.D., Rupert, A.H., & Kelley, A.M. (2013). Mental Disorders Comorbid with Vestibular Pathology. Psychiatry Annals, 43(7), 324-327.

Kelley, A. Cheung, B., Lawson, B., Rath, E., Chiasson, J., Ramiccio, J., & Rupert, A. (2013). Efficacy of directional cues from a tactile system for target orientation during helicopter extractions over moving targets (Report No. 2013-09). Fort Rucker, AL: USAARL.

Drs. Rupert presented “Designing tactile displays to optimize training and ensure veridical perceptions in sensory altered environments,” by Rupert, A.H, and Lawson, B.D. (2012). Human Factors and Ergonomics Society’s 56th Annual Meeting, 22-26 Oct 2012, Boston, MA. (To be published in the Journal of Human Factors and Ergonomics).

Dr. Cheung presented “Efficacy of directional tactile cues for target orientation during helicopter extractions over moving targets.” Abstracts of the Aerospace Medical Association (AsMA) 84th Annual Scientific Meeting. May 12-16, 2013. Chicago, Illinois. Aviation, Space, and Environmental Medicine, (84)4, 368.

Dr. Lawson presented “A tacton for object approach,” by Lawson, B.D., Rupert, A.H., Cholewiak, R., & Legan, S. (2012). Presentations as part of the expert discussion panel

Multisensory and Tactile Systems for Soldiers: Theory, Research, and Applications, Human Factors and Ergonomics Society's 56th Annual Meeting, 22-26 Oct 2012, Boston, MA.

Dr. Lawson presented "Epidemiological Study of MTBI among different MOSs." Lawson, B.D., & Cho, T.H. Frederick, MD. 19 Sept., 2012.

Dr. Lawson presented "Post-Concussive Rehabilitation, Treatment, and Fitness for Duty." Rupert, A.H. and Lawson, B.D. (2012). Concussion Prevention In Progress Review, MRMC, Fort Detrick, MD, Sept. 2012.

Dr. Lawson presented "Development of Fitness for Duty Assessment Battery for Recovering Dismounted Warriors." Lawson, B.D. (2013). Slide presentation for MRMC R&A., USAARL, 7 March 2013.

Dr. Lawson presented "Traumatic Brain Injury (TBI) Deficits Likely to Disrupt Tasks Required by Specific Military Occupational Specialties (MOSs)." Lawson, B.D., & Cho, T.H. (2013). MOMRP Core. Epidemiological study. Slide presentation for MRMC R&A., USAARL, 7 March 2013.

Dr. Lawson presented "Multisensory Balance Cueing: Research and Demonstration." Lawson, B.D., & Rupert, A.H. (2013). Brief to BG Timothy Gowen, Deputy Commanding General, 29th Infantry Division (Light), Ft. Belvoir, VA. Also briefed Director of the Naval Aviation Center for Rotorcraft Advancement (U.S. NavAir SysCom), Pax River, MD. USAARL, both on 12 March 2013.

Drs. Rupert and Lawson gave several presentations 25 April 2013, on the following:

Rupert, A.H., & Lawson, B.D. TSAS for Orientation During Aviation and Balance: Current Projects, Needs, Plans, and International Transition Opportunities. USAARL, 25 April 2013. Presentation to the following people:

LTCOL Mark Adams, U.K. Exchange Officer, USAARL.

COL Andy Jose, U.K. Liaison Officer to the Medical Office of the U.S. Army Surgeon General.

COL Leshinska, Director, Rotary Wing Development, Capability Development Group, Australian Dept. of Defence.

LTCOL Stephen Jobson, Australian Liaison Officer to the U.S. Army Aviation Center of Excellence (USAACE).

LTCOL Erick Merck, French Liaison Officer to USAACE and Fort Rucker.

Drs. Lawson and Rupert presented "Overview of Research Projects." Lawson, B.D., & Rupert, A.H. Presentation to BG Caravalho. USAARL, 24 April 2013.

Drs. Rupert and Lawson presented "Status of Nine Product Development Efforts." Rupert, A.H., & Lawson, B.D. Presentation and Demonstrations to Dr. Betram. USAARL, 24 April, 2013.

Drs. Ranes and Lawson presented “Development of Task P Clinical Toolkit.” Ranes, B., & Lawson, B.D. Presentation to BG Caravalho. USAARL, 24 April 2013.

Drs. Lawson and Rupert presented “Tactile Cueing for Balance and for Infantry Communication.” Rupert, A.H., & Lawson, B.D. Briefing and demonstrations to COL R.M. Smith, L/RA, U.K. Asst. Military Attaché. USAARL, 1 May, 2013.

Dr. Lawson presented “Overview of Research Projects.” Lawson, B.D. Presentation and demonstration to two visiting professors from Troy State Univ. USAARL, 15 May 2013.

Drs. Lawson and Rupert presented “Overview of Research Projects.” Lawson, B.D., & Rupert, A.H. Briefings and demonstrations to COL Stockhausen and his family. COL Stockhausen is Director, TRADOC Program Office-Aviation Brigades, USAACE. Briefings at USAARL, 29 May, 2013.

Dr. Copeland of AMRDEC presented “Tactile Cueing Applications for Aviation. Presentations to Ms. Shyu, Army Acquisition Executive. 18 July 2013, Washington, DC.

Drs. Lawson and Rupert presented “Overview of Research Activities.” Presentation and demonstrations to Drs. Muth and Mr. Wilson of Clemson University, 18 June 2013, USAARL.

Drs. Rupert and Lawson presented “Command Project Briefings.” Four presentations to incoming Commanding Officer COL Smyrski, 24 June, 2013, USAARL.

Drs. Rupert and Lawson presented “Overview of Research Activities.” Presentation and demonstrations to COL Renteria, USACE Command Surgeon, 1 July 2013, USAARL.

Dr. Rupert presented “Postconcussion Rehabilitation, Treatment, and Fitness for Duty.” Rupert, A.H. & Lawson, B.D. Presented to the MOMRP Joint Program Committee Meeting for Concussion Research In Progress Review, 23 July, 2013, Fort Detrick, MD.

Dr. Lawson and Rupert presented “Tactile Cues for Helping the Military.” Presentations and demonstrations to three groups of Fort Rucker Elementary School teachers, 26 Aug, 2013, USAARL.

COL Smyrski briefed BG Edens (USACR/SC) regarding spatial disorientation, partly based on inputs from USAARL investigators such as Drs. Crowley, Rupert, Estrada, Lawson, etc. 21 Aug, Fort Rucker.

Drs. Rupert and Lawson presented “Research Applications in Development.” Presentation and demonstrations to the Auburn University MRC Center visitors, 4 Sept 2013, USAARL.

Drs. Lawson and Rupert presented “Simple Field Test and Balance Rehabilitation Efforts.” Presentation to HCOE San Antonio visitors, 11 Sept, 2013, USAARL.

Drs. Rupert and Lawson presented “Tactile Balance Rehabilitation.” Presentation to Dr. Stasi, of the University of Granada and the Spanish Army Training and Doctrine Command, 17 Sept 2013, USAARL.

Drs. Rupert and Lawson presented “Tactile Research Applications.” Presentation and demonstrations to Dr. Lewis and Mr. Lewis of AMRDEC, 18 Sept, 2013, USAARL.

Drs. Lawson and Rupert presented “Ongoing Research Activities.” Presentation and demonstrations to Navy CAPT Andrews and Dr. Arnold of NMRU-D Dayton, 18 Sept, 2013, USAARL.

- **Website(s) or other Internet site(s).** Nothing to Report.

- **Technologies or techniques.** Nothing to Report.

- **Inventions, patent applications, and/or licenses.**

SYSTEM AND METHOD FOR VIBROTACTILE GUIDED MOTIONAL TRAINING	Gary Zets Bruce Mortimer Karen Atkins	Issued 8,092,355
10-5169 **ENHANCED SYSTEM AND METHOD FOR VIBROTACTILE GUIDED THERAPY**	Gary Zets Bruce Mortimer	Pending (Non-Publication) Appl. No 13/300,333 Filed 11/18/2011

10-5170 **MULTIMODAL SENSORY FEEDBACK SYSTEM AND METHOD FOR TREATMENT AND ASSESSMENT OF DISEQUILIBRIUM, BALANCE AND MOTION DISORDERS**	Gary Zets Bruce Mortimer	Pending (Non-Publication) Appl. No 13/306,872 Filed 11/29/2011

11-6194 **ENHANCED SYSTEM AND METHOD FOR ASSESSMENT OF DISEQUILIBRIUM, BALANCE AND MOTION DISORDERS** **(Headshake)**	Gary Zets Bruce Mortimer	Pending (Non-Publication) Appl. No 13/300,428 Filed 11/18/2011

- **Other Products.** Nothing to Report.

7. **PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:**

- **What individuals have worked on the project?**

Name:	Dr. Angus Rupert
Project Role:	Principle Investigator
Nearest person month worked:	15

Contribution to Project:	Proposal writing, IRB and joint approval between services, meetings, and writing papers.
Funding Support:	Coalition Warfare Program, MRMC core funded projects.

Name:	Dr. Ben Lawson
Project Role:	Associate Investigator
Nearest person month worked:	15
Contribution to Project:	Proposal writing, IRB and joint approval between services, meetings, and writing papers.
Funding Support:	MRMC core funded projects

Name:	Dr. Kim Gottshall
Project Role:	Associate Investigator
Nearest person month worked:	20
Contribution to Project:	IRB protocol, patient data collection.
Funding Support:	Navy GS civilian physiotherapist.

Name:	Dr. Grant Meisenholder, PhD
Project Role:	Physiotherapist
Nearest person month worked:	24
Contribution to Project:	Data collection
Funding Support:	CDMRP

Name:	Professor Bruce Mortimer
Project Role:	Electrical Engineer

Nearest person month worked:	13
Contribution to Project:	Designing biofeedback balance platform.
Funding Support:	SBIR support

Name:	Dr. Karen Atkins, PhD
Project Role:	CEO Balance Sense, PhD physiotherapy
Nearest person month worked:	36
Contribution to Project:	Design and test of balance platform; data collection.
Funding Support:	SBIR support

Name:	Casey Harris
Project Role:	Technician
Nearest person month worked:	12
Contribution to Project:	Assembly platforms & software.
Funding Support:	Coalition Warfare Program

Name:	John Chiasson
Project Role:	Software & firmware engineer
Nearest person month worked:	15
Contribution to Project:	Software and hardware design and support.
Funding Support:	Coalition Warfare Program

- **Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?**
  - Nothing to Report.

- **What other organizations were involved as partners?**

Organization Name:	Navy Medical Center San Diego (NMCSD)
Location of Organization:	San Diego, CA
Partner's contribution to the project:	Data Collection Center

Organization Name:	Engineering Acoustics Inc. (EAI)
Location of Organization:	Orlando, FL
Partner's contribution to the project:	Equipment development; SBIR phase II recipient to develop tactile cueing balance platforms.

Organization Name:	Balance Sense
Location of Organization:	Orlando, FL
Partner's contribution to the project:	Equipment Development SBIR Phase II recipient to develop balance platform with tactile cueing.

Organization Name:	Headley Court
Location of Organization:	UK
Partner's contribution to the project:	Clinical evaluation of balance platforms for manufacturers
Facilities (e.g., project staff use the partner's facilities for project activities):	Facility similar to U.S. Center for Intrepid treating mTBI, blast and multi trauma soldiers;

Organization Name:	Veterans Administration (VA)
Location of Organization:	Pensacola, FL
Partner's contribution to the project:	Beta testing of balance platforms

8. **SPECIAL REPORTING REQUIREMENTS**

- **QUAD CHART:** Please see Appendix B (p. 39).

9. **APPENDICES:**

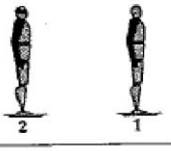
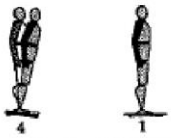
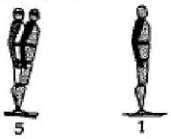
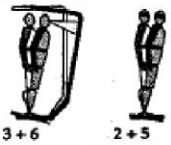
APPENDIX A.

Neurocom Equitest Sensory Organization Test (SOT) and Berg Balance Scale

1) SOT

The Interpretation of Computerized Dynamic Posturography Tests (from Nashner, in Jacobson, Newman, & Kartush, 1997.

The functional significance of different Equitest conditions:

SENSORY ANALYSIS			
RATIO NAME	**TEST CONDITIONS**	**RATIO PAIR**	**SIGNIFICANCE**
SOM Somatosensory	 2 1	Condition 2 / Condition 1	**Question:** Does sway increase when visual cues are removed? **Low scores:** Patient makes poor use of somatosensory references.
VIS Visual	 4 1	Condition 4 / Condition 1	**Question:** Does sway increase when somatosensory cues are inaccurate? **Low scores:** Patient makes poor use of visual references.
VEST Vestibular	 5 1	Condition 5 / Condition 1	**Question:** Does sway increase when visual cues are removed and somatosensory cues are inaccurate? **Low scores:** Patient makes poor use of vestibular cues, or vestibular cues unavailable.
PREF Visual Preference	 3+6 2+5	Condition 3 + 6 / Condition 2 + 5	**Question:** Do inaccurate visual cues result in increased sway compared to no visual cues? **Low scores:** Patient relies on visual cues even when they are inaccurate.

Examples of Diagnostic and Functional Applications of CDP:

Test Modality	Applications: Diagnostic	Applications: Functional
Response latencies	Peripheral nerve, spinal cord, and brain stem lesions	None documented
Response strengths	Cerebellar deficits (muscle weakness, nerve injuries)	Automatic motor adaptation
Sensory organization test patterns	Vestibular system dysfunction, positive evidence for symptoms exaggeration	Overall balance and sensory adaptive capabilities
Strategy analysis	None documented (ankle muscle weakness, distal sensory losses)	Movement control adaptive capabilities
Center of gravity alignment	None documented (reduced range)	Perception of vertical

Additional details concerning the CDP procedure and interpretation (from a paper in preparation by the PI):

A NeuroCom Smart EquiTest® model will be used for the posturography testing. The Sensory Organization Test (SOT) will be used. The subject stands on a force plate platform that can be fixed or moved, surrounded on three sides by a visual display that also could be fixed or moved. Subjects wear stockings without shoes during testing. The platform can rotate in the anterior/posterior axis, with its axis of pitch rotation roughly passing through the medial malleoli of the subject. The visual surround may rotate in a similar fashion. By using different combinations of platform fixed/moveable, visual surround fixed/moveable, and eyes open/closed, it is possible to quantify the performance of each of the three balance systems. The force plate calculates the center of pressure for the subject's feet and using this information and the subject's height, calculates the degrees of rotation of the body's center of gravity (COG) away from the vertical. This measure is termed body sway. During testing, the subject wears a safety harness. The harness connects (near the shoulders) to an overhead support via two straps. The straps remain slack for the normal range of stable body movements and do not support the subject; however, the straps will catch the subject should the stable range of motion be exceeded. Subjects wear an aviation-style audio headset that delivers pink noise (to mask background sounds that may provide orientation cues) and a metronome bell to signal the subject for head movements during the ±30° dynamic head pitch testing. The headset is fitted with an Intersense InertiaCube orientation sensor to monitor the subject's head position.

Scoring Procedure: All six standard SOT tests are performed in a normal upright stance with arms folded and head held upright. Each subject performs three trials of 20

seconds duration during each of the 6 standard SOT conditions, making a total of 18 trials for the standard baseline. An equilibrium score is calculated for each trial. Scores are calculated by using the maximum amount of peak to peak body sway, in degrees of sway angle, recorded during a 20 second trial using the following equation.

The constant (12.5) is the theoretical maximum anteroposterior sway angle, for stable upright posture. Greater the peak-to-peak body sway results in a lower the Equilibrium Score. A score of 100 indicates perfect stability while a score of zero indicates a fall. If the subject loses balance during a trial, by stepping, stumbling, reaching out and touching the surround, or gaining support from the safety harness, the test is terminated by the operator and classified as a fall.

A composite equilibrium score is calculated for each subject based on the three trials each of head-upright SOT conditions 1-6. The composite equilibrium score is calculated by independently averaging the scores for conditions 1 and 2, adding these two scores to the equilibrium scores from each trial of sensory conditions 3, 4, 5, and 6, and dividing the sum by 14. The highest possible composite equilibrium score is 100.

Normal or abnormal performance was determined by comparing scores for each subject to a normative database. The NeuroCom normative database provided standards for a head-upright SOT. The following age ranges are evaluated by NeuroCom: 20-59 years, n=112; 60-69 years, n=54; and 70-79 years, n=29. The age range divisions are based on statistically significant differences in performance by the different groups. Normal thresholds are calculated for each age group by percentile ranking the three-trial-average scores for each subject. The value of the 5th percentile score is considered to be the limit of normal performance. Scores below this value are defined as abnormal.

The present study will test the effects of head movement on the performance of SOTs 2 and 5. Dynamic 30-degree motions will be made while balancing. Subjects are instructed to move their heads to the forward position (+30º tilt), then return to upright, then to the backward position (-30º tilt), then return to upright. A metronome bell will sound at 1 second intervals through the subject's headset to alert the subject that it was time to change head position. It will take four seconds it takes to make a complete cycle. Head movement will be monitored with a three-dimensional inertia sensor mounted to head phones (InertiaCube2, InterSense, Inc.; Burlington, MA). Sensor output is displayed on the operator console. Head pitch amplitude is monitored at the start of each trial for 1-2 cycles to ensure the correct amplitude is generated by the subject, with the operator providing feedback as needed. Subjects stand with their arms folded and performed six trials each of SOTs 2 and 5 under each head-movement condition.

Mean SOT scores were calculated for each subject under each condition. Specifically, three-trial averages were calculated for SOTs 1-6 (head erect) and six-trial averages for SOTs 2 and 5 (with head moving). NeuroCom software scores all falls as a zero and counts them in the mean score. This analysis limitation is not of major concern when considering stable platform testing with healthy persons, where the probability of falls is extremely low. However, the present study will also analyze performance during unstable platform conditions, often using patient groups or challenging head movement protocols; hence, fall counts will be interpreted separately from sway scores during analysis.

2) Berg Balance Test

Berg Balance Scale

The Berg Balance Scale (BBS) was developed to measure balance among older people with impairment in balance function by assessing the performance of functional tasks. It is a valid instrument used for evaluation of the effectiveness of interventions and for quantitative descriptions of function in clinical practice and research. The BBS has been evaluated in several reliability studies. *A recent study of the BBS, which was completed in Finland, indicates that a change of eight (8) BBS points is required to reveal a genuine change in function between two assessments among older people who are dependent in ADL and living in residential care facilities.*

Description:
14-item scale designed to measure balance of the older adult in a clinical setting.

Equipment needed: Ruler, two standard chairs (one with arm rests, one without), footstool or step, stopwatch or wristwatch, 15 ft walkway

Completion:

Time: 15-20 minutes

Scoring: A five-point scale, ranging from 0-4. "0" indicates the lowest level of function and "4" the highest level of function. Total Score = 56

Interpretation:
41-56 = low fall risk
21-40 = medium fall risk
0 –20 = high fall risk

A change of 8 points is required to reveal a genuine change in function between 2 assessments.

Berg Balance Scale

Name: _____ Date: _____

Location: _____ Rater: _____

ITEM DESCRIPTION	SCORE (0-4)
Sitting to standing	_____
Standing unsupported	_____
Sitting unsupported	_____
Standing to sitting	_____
Transfers	_____
Standing with eyes closed	_____
Standing with feet together	_____
Reaching forward with outstretched arm	_____
Retrieving object from floor	_____
Turning to look behind	_____
Turning 360 degrees	_____
Placing alternate foot on stool	_____
Standing with one foot in front	_____
Standing on one foot	_____

Total _____

GENERAL INSTRUCTIONS

Please document each task and/or give instructions as written. When scoring, please record the lowest response category that applies for each item.

In most items, the subject is asked to maintain a given position for a specific time. Progressively more points are deducted if:

- the time or distance requirements are not met
- the subject's performance warrants supervision
- the subject touches an external support or receives assistance from the examiner

Subject should understand that they must maintain their balance while attempting the tasks. The choices of which leg to stand on or how far to reach are left to the subject. Poor judgment will adversely influence the performance and the scoring.

Equipment required for testing is a stopwatch or watch with a second hand, and a ruler or other indicator of 2, 5, and 10 inches. Chairs used during testing should be a reasonable height. Either a step or a stool of average step height may be used for item # 12.

Berg Balance Scale

SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hand for support.
( ) 4 able to stand without using hands and stabilize independently
( ) 3 able to stand independently using hands
( ) 2 able to stand using hands after several tries
( ) 1 needs minimal aid to stand or stabilize
( ) 0 needs moderate or maximal assist to stand

STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding on.
( ) 4 able to stand safely for 2 minutes
( ) 3 able to stand 2 minutes with supervision
( ) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported
( ) 0 unable to stand 30 seconds unsupported

If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.

SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes.
( ) 4 able to sit safely and securely for 2 minutes
( ) 3 able to sit 2 minutes under supervision
( ) 2 able to able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

STANDING TO SITTING
INSTRUCTIONS: Please sit down.
( ) 4 sits safely with minimal use of hands
( ) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent
( ) 1 sits independently but has uncontrolled descent
( ) 0 needs assist to sit

TRANSFERS
INSTRUCTIONS: Arrange chair(s) for pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands
( ) 3 able to transfer safely definite need of hands
( ) 2 able to transfer with verbal cuing and/or supervision
( ) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.
( ) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision
( ) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays safely
( ) 0 needs help to keep from falling

STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding on.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand 1 minute with supervision
( ) 2 able to place feet together independently but unable to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together
( ) 0 needs help to attain position and unable to hold for 15 seconds

Berg Balance Scale continued…

REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at the end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the fingers reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)

( ) 4 can reach forward confidently 25 cm (10 inches)
( ) 3 can reach forward 12 cm (5 inches)
( ) 2 can reach forward 5 cm (2 inches)
( ) 1 reaches forward but needs supervision
( ) 0 loses balance while trying/requires external support

PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION
INSTRUCTIONS: Pick up the shoe/slipper, which is in front of your feet.

( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5 cm(1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
INSTRUCTIONS: Turn to look directly behind you over toward the left shoulder. Repeat to the right. (Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.)

( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

TURN 360 DEGREES
INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.

( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cuing
( ) 0 needs assistance while turning

PLACE ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED
INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times.

( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps in > 20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete > 2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

STANDING UNSUPPORTED ONE FOOT IN FRONT
INSTRUCTIONS: (DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width.)

( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

STANDING ON ONE LEG
INSTRUCTIONS: Stand on one leg as long as you can without holding on.

( ) 4 able to lift leg independently and hold > 10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold ≥ 3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently.
( ) 0 unable to try of needs assist to prevent fall

( ) TOTAL SCORE (Maximum = 56)

www.aahf.info/pdf/Berg_Balance_Scale.pdf

Appendix B.

Quad chart

Title: Post Concussive Rehabilitation, Treatment, and Fitness for Return to Duty
Proposal ID, Funding Source: W81XWH-09-2-0182 CDMRP

PI: A Rupert **Org:** Henry Jackson Foundation **Award Amount:** $590

Study/Product Aims

- Combine tactile cueing with visual and auditory stimuli as a multisensory feedback tool to improve balance rehabilitation.
- Develop portable system for clinical use.
- Conduct preclinical trial data with mTBI patients to demonstrate efficacy of tactile cueing and support full multicenter clinical trial.

Approach

Leveraging SBIR phase II funding, the program developed a small portable tactile cueing feedback device that also incorporates auditory and visual feedback to improve balance rehabilitation of patients with mTBI including amputees.

By incorporating head-movement protocols the device can also provide initial assessment and measure improvement between treatments.

Accomplishment: Clinical data collection using the final prototypes was begun FY13. Data collection completed using 40 patients

Timeline and Cost

Activities CY	10	11	12	13	14
Product development.					
Initial testing on mTBI patients.					
Modification of device and retest.					
Data collection and analysis.					
Estimated Budget ($K)	**$40.1**	**$64.5**	**$105.5**	**$153**	**$227**

Updated: December 21st 2014

Goals/Milestones

CY 10 Goal – Develop new hardware to provide multisensory cueing
☑ Integrate visual and auditory components with tactile cueing.
CY11 Goals – Complete prototype and initiate testing on mTBI patients.
☑ Integrate visual and auditory components with tactile cueing.
☑ Initiate testing of prototypes with Physiotherapist's feedback to modify.
CY12 Goal – Final Prototype with modifications.
☑ Device modified and tested using mTBI patients.
CY13 Goals – Commence data collection using mTBI patients.
☐Data Collection in progress
CY14.Goals --- Complete data collection, Analysis and report

Appendix C.

Letters of Support

1) Naval Medical Center San Diego (NMCSD)

C5 VESTIBULAR PHYSICAL THERAPY DIVISION
DEPARTMENT OF PHYSICAL AND OCCUPATIONAL THERAPY
NAVAL MEDICAL CENTER SAN DIEGO
SAN DIEGO, CA 92134

Kim Gottshall
Naval Medical Center
34800 Bob Wilson Drive
San Diego, CA 92134
619-532-7450

To Whom It May Concern,

Thank you for the opportunity to relay the effectiveness of the Sensory Enrichment Multimodal Device (SEMD) by BalanceSense. The SEMD has been utilized in evaluation and treatment over the last five years. SEMD has become an important tool in the rehabilitation protocol for our troops recovering from blast and blunt trauma, as well as our patients with balance deficits from other sources.

SEMD accommodates relearning control of postural sway in sitting, standing and tandem tasks. Tactile and visual feedback reinforces the progression of the patient from the low level of wheelchair mobility, to static standing, to dynamic mobility activities such as heel-to-toe walking.

Complex poly trauma patients with both head injury and limb amputation benefit from the cues afforded by SEMD when relearning previous mobility requirements within the construct of their new balance dynamics. Rehabilitation specialists traditionally used verbal cues which require cognitive processing on the part of the patient. The key to SEMD's approach is vibrotactile continuous, relevant feedback. Brain injury patients use SEMD to relearn balance skills of stance and stride without the requirement of central auditory processing of verbal commands.

Patients report the visual and vibrotactile cueing is easy to follow, and that SEMD's sensory enrichment provides a reinforcement of correct postural adaptation for accomplishment of sit to stand, as well as steady stance. The vibrotactile cueing delivers sway information that the vestibular system integrates with proprioception when standing with eyes closed vision eliminated. Amputee patients with altered proprioception incorporate SEMD's sway guidance when relearning parameters of weight shift onto a prosthetic leg to avoid over leaning that would result in a fall, or under leaning and not being able to step.

Progression of task difficulty options include eyes open static parallel stance to eyes closed unilateral stance. Foam of various densities can be placed on the force platform, during dual tasking and spatial orientation activities available in the software applications. A favorite activity is maintaining center of gravity while standing with eyes closed on an added platform accessory rotating disc or rocker board. In addition, the dual task word game, and the weight shifting movement to drive a toy car is engaging for cognitively impaired patients as they are able to incorporate advanced tasking .

The physical therapy students that intern in the clinic readily accept the SEMD advanced technology, and find it user friendly as a cutting edge rehabilitation device beneficial to balance patients. When asked which equipment they would consider as "must have" in their own clinics, SEMD is always included.

Very respectfully,

Kim Gottshall PhD PT, COL USA (ret)
Director, Vestibular and Balance Rehabilitation
Naval Medical Center, San Diego

2) Department of Physical Therapy Neurological Rehabilitation Group

Department of Physical Therapy
Neurological Rehabilitation Group
Defence Medical Rehabilitation Centre
Headley Court
Epsom, Surrey, KT18 6JW
Telephone: (01372) 378271 Ext: 7234

To whom it may concern, 13th August 2013.

We have been using the BalanceSense Vibrotactile device within Neurophysiotherapy as an adjunct for rehabilitation for a range of patients with balance, vestibular and movement control disorders. We have utilised all aspects of the device including the vibrotactile belt, dual tasking elements and the car.

The BalanceSense is of particular therapeutic benefit for this patient group. We have used the Balance Sense to retrain movement control in patients with ataxia and impairments of motor control as well as patients with high level balance and vestibular dysfunction. The visual display of movement on screen provides the patient with real time feedback as to how they are moving, the degree of movement excursion outside a target area, and in which direction the patient is moving/weight-bearing. It encourages correction of alignment and weight-bearing at a fine postural control level to address excess movement. Used in conjunction with the vibrotactile belt patients gain a greater insight into how their balance is affected. This enhances recovery of both static and dynamic control of postural sway.

The ability to record the movement and play back is of great value especially when working with eyes closed. Patients do not always realise how far they move in the control of balance and during an apparent static task and having the ability to replay aids their understanding. Also patients like to be able to improve upon their previous efforts, which the play back facility supports by charting progress, unlike more traditional methods of balance rehabilitation such as balance boards.

The vibrotactile belt allows the patient to 'feel' in which direction they are moving and gives them a prompt for fine control of posture, especially when they have eyes closed. For the majority of patients with vestibular disorders the ability to balance with eyes closed is significantly difficult. The vibrotactile belt aids rehabilitation in this area. The belt provides a tactile response to movement outside of a target area which increases patient awareness of their balance control.

The Word Game incorporates dual tasking into rehabilitation by challenging the patient cognitively through the spelling task and from a postural point of view by making the patient move to each target letter. The patients find dual tasking particularly difficult given the level of concentration required for balance alone. The Word Game has been of benefit to our patients in this respect.

The car provides an opportunity for patients to work on both dynamic balance and postural control via utilising weight shifting to steer the car. There is also a considerable element of developing spatial awareness outside of the patient's immediate environment when moving the car around a large space. Patients need to be able to relate the car's movement to their own movement which is a task that works on cognition, spatial orientation and fine dynamic control. Finally the car also aids cognitive rehabilitation due to the complexity of the task involved in steering a car via weight-shifting and rapid changes of orientation required. The car is the element the patients enjoy the most. It engages their interest more than the Word Game and anecdotally their fine movement control improves considerably during the task. We have also seen increased movement during the car task from patients with vestibular and/or balance dysfunction who are reluctant to move out of their base of support in other circumstances.

The device is user-friendly and the therapy staff finds they are able to switch between tasks with ease during a session as required.

Appendix C. (continued)

Letters of Support

The low platform allows easy access for the more dependent patients. There is the potential for use of the Balance Sense with more physically impaired patients to analyse weight-bearing and weight-shifting in sitting and tasks such as sit to stand.

The therapy staff finds that it enhances their ability to analyse movement at a postural adjustment level which is hard to assess just by looking. The therapists can see if there is a bias towards asymmetrical weight-bearing in real time and either prompt the patient to correct or observe any independent postural adjustments

Overall the Balance Sense has been of benefit therapeutically to our cohort of patients. The patients have demonstrated improvements in balance scores including Functional Gait Assessment and have demonstrated a reduction of vestibular symptoms.

Yours faithfully

Georgina Hughes

Team Leader for Neurophysiotherapy